

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PAT 9030/060-PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2006/000145	International filing date (<i>day/month/year</i>) 10 January 2006 (10.01.2006)	Priority date (<i>day/month/year</i>) 11 January 2005 (11.01.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant CARL ZEISS MEDITEC AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 17 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 14 August 2007 (14.08.2007)
Facsimile No. +41 22 338 82 70	Authorized officer <div style="text-align: center; font-weight: bold;">Agnes Wittmann-Regis</div> e-mail: pt06.pct@wipo.int

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

Applicant's or agent's file reference
PAT 9030/060-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/EP2006/000145

International filing date (day/month/year)
10.01.2006

Priority date (day/month/year)
11.01.2005

International Patent Classification (IPC) or both national classification and IPC
A61F9/009

Applicant
CARL ZEISS MEDITEC AG

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
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| <input checked="" type="checkbox"/> | Box No. II | Priority |
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| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
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2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP:	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2006/000145

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

See Supplemental Box

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☒ all parts
- ☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-6, 10, 11, 13, 14, 16, 19, 20, 22</u>	YES
	Claims	<u>7-9, 12, 15, 17, 18, 21</u>	NO
Inventive step (IS)	Claims	<u>10, 11, 14, 16, 19-20, 22</u>	YES
	Claims	<u>1-6, 7-9, 12, 13, 15, 17, 18, 21</u>	NO
Industrial applicability (IA)	Claims	<u>1-22</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

1 Citations

Reference is made to the following documents:

- D1: EP-A-0 589 825 (OPTIKO SCIENTIFIC LTD; OPTIKO SCIENT LTD) 30 March 1994 (1994-03-30)
- D2: US-A-5 217 452 (O'DONNELL ET AL) 8 June 1993 (1993-06-08)
- D3: DE 198 31 674 A1 (LASERFORUM GMBH FORUM FUER LASERCHIRURGIE DES AUGES - KOELN) 20 January 2000 (2000-01-20)
- D4: EP-A-0 608 052 (INTELLIGENT SURGICAL LASERS, INC) 27 July 1994 (1994-07-27)
- D5: EP-A-1 570 822 (20/10 PERFECT VISION OPTISCHE GERAETE GMBH) 7 September 2005 (2005-09-07)

2 Independent claim 1

- 2.1 The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 1 does not involve an inventive step (PCT Article 33(3)).

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
2.2	<p>Document D1 is considered to be the prior art closest to the subject matter of claim 1. Said document discloses:</p> <p>A laser treatment apparatus for eye surgery (column 2, lines 46-49), with a head support for a patient and a contact lens that can be placed onto the eye (column 4, lines 17-21), through which lens a treatment laser beam passes (column 4, lines 1-3), wherein a safety mechanism is provided, which moves the head support and the contact lens apart when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens (see "pressure control unit 53" in column 4, lines 21-28: the motor is controlled via the force measuring unit and can therefore be set so that the motor is not activated below a threshold value), characterized in that the safety mechanism facilitates the movement apart only in the event of a force above a force threshold value and in the event of a force below the force threshold value fixes the head support and the contact lens relative to one another (see "pressure control unit 53" in column 4, lines 21-28: since the "pressure control unit" measures the pressure applied to the eye and controls the motor depending on the measured value, any force threshold value can thus be set).</p> <p>2.3 The subject matter of claim 1 differs therefore from that known from D1 in that the use of a chin or forehead support or other contact surface for</p>

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

the head is not explicitly mentioned.

However, the use of such a head contact surface is generally known. According to the examiner's knowledge, neither any apparatus for examining or treating the retina nor any apparatus in the Femtosecond Lasik field is currently in use that does not provide a head contact surface.

The presence of such a contact surface is therefore considered so obvious that it is no longer mentioned in the prior art for this reason alone. In the description of D2, cited here as an example, no details are given of a head support, but figures 3 and 4 show very well the presence of such a support.

- 2.4 The present application does not therefore satisfy the requirements of PCT Article 33(1), because the subject matter of claim 1 does not involve an inventive step (PCT Article 33(3)).

3 Independent claim 7

The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 7 is not novel (PCT Article 33(2)).

Document D4 discloses:

A laser treatment apparatus for eye surgery (abstract), with a head support for a patient (figures 1-3: it is implicitly disclosed that such a head support is present, as it cannot be assumed that the patient shown in the

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

figures is floating in the air), a beam deflection unit, which deflects a treatment laser beam variably at least about one axis (see "means for moving said focal point along a preselected path relative to said contact lens to perform said surgery" in claim 1), focusing optics, which are arranged following the beam deflection unit and focus the laser beam into or onto the eye along an optical axis (column 3, lines 11-18 & lines 45-51 & figure 1), a contact lens that can be placed onto the eye and is arranged following the focusing optics (column 6, lines 8-23 & column 3, lines 7-10 & figure 1), and a safety mechanism, which moves the head support and the contact lens apart when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens ("compensating device; spring 36a,b" in column 5, lines 7-31), characterized in that the beam deflection unit is arranged at least with respect to a deflection element acting for one axis of deflection in the entrance pupil of the focusing optics (see the clarity objection in Box VIII relating to this; to the extent to which the feature is comprehensible, it appears to be disclosed in column 3, lines 7-18 and figures 1,2) and the safety mechanism couples the contact lens, the focusing optics and the deflection element such that on the movement apart the deflection element remains in the entrance pupil and the length of the optical path between the deflection element and the contact lens is constant (see the clarity objection in Box VIII relating to this; to the extent to which the feature is comprehensible, it appears to be disclosed in column 5, lines 1-6, in that "the relationship between housing 12 and base 28 of mechanism 16" is fixed).

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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4	Independent claim 17
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The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 17 is not novel (PCT Article 33(2)).

Document D1 discloses:

A laser treatment apparatus for eye surgery (column 2, lines 46-49), with a contact lens that can be placed onto the eye (column 4, lines 17-21), through which lens a treatment laser beam passes (column 4, lines 1-3), and a safety mechanism, which holds the contact lens movably ("spring assembly 52" in column 4, lines 21-28 & lines 36-40 & figure 2), so that when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens, this retreats (column 3, lines 22-31 & column 4, lines 17-28), characterized in that the safety mechanism has a detector device, which monitors a retreat of the contact lens ("pressure control unit 53" in column 4, lines 21-28 & figure 2) and in the event of a movement of the contact lens exceeding a threshold value interrupts a laser treatment operation of the laser treatment apparatus (column 3, lines 22-31 & column 4, lines 17-28).

5 Dependent claims 8-9,12,15,18,21

Claims 8-9,12,15,18,21 do not contain any features which, in combination with the features of any claim to which they refer back, satisfy the PCT requirements for novelty.

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

- Claim 8: See D4, column 2, line 41 - column 3, line 6.
- Claim 9: See D4, column 2, line 41 - column 3, line 18.
- Claim 12: See "linear spring force" in column 2, lines 52-57 in D4.
- Claim 15: See D4: a force on the "frame member" in column 2, line 41 - column 3, line 6 causes a movement apart of the safety mechanism.
- Claim 18: See D1: the "pressure control unit 53" in column 4, lines 17-28 is suitable for moving the contact lens and eye apart as soon as a predetermined force threshold value is reached.
- Claim 21: As shown in figure 2 of document D1, the pressure detector is fastened to the housing and thus detects the pressure of the eye onto the housing. See also column 3, lines 22-31 & column 4, lines 17-28.

6 Dependent claims 2-5,13

Claims 2-5,13 do not contain any features which, in combination with the features of any claim to which they refer back, satisfy the PCT requirements for inventive step.

- Claim 2: See D1: column 4, lines 21-28 & figure 1.
- Claim 3: See D1, "measurement of pressure" in column 4, lines 21-28.
- Claim 4: See D1: the "spring assembly 52", column 4, lines 17-28 and figure 2, is pressed with a force onto the holding element "housing 2b", column 4, lines 17-21. If a predefined force is

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Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
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exceeded, the motor "M" is set in motion.

Claim 5: See D1, "treating the eye..." in column 2, lines 46-49: if an eye is to be treated with the laser beam, it is implicitly disclosed that the beam must be focused, otherwise meaningful treatment would not be possible.

Claim 6: See D4, column 5, line 26.

Claim 13: See D3, column 4, lines 43-47. It is provided that the "magnetic current [is] electronically monitored", thus the force threshold value can be set via the magnetic current.

7 Dependent claim 22

Document EP1570822 (D5) is cited as a "P" document and is thus not relevant as prior art if the claimed priority is valid. However, since no valid priority document exists up to now and the validity of the priority cannot therefore be verified, the applicant is hereby advised of objections possibly resulting with regard to inventive step in connection with document EP0608052 (D4) in respect of claim 22:

Claim 22: See also clarity objection in Box VIII.

Notwithstanding this, D5 discloses in paragraph [0041] that, on attaining a certain force value, no further approach of the chair to the laser is possible. Rather only an active increase in this distance between eye and laser is provided.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
EP1570822	07.09.2005	17.01.2005	1.03.2004

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2006/000145

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The application does not satisfy the requirements of PCT Article 6, because claims 7, 13, 14 and 19-22 are not clear.

Claim 7: The claim is unclear, since there is no clear definition of the term "entrance pupil of focusing optics": on the one hand, the illuminated diameter of the first lens could be considered the entrance pupil of the focusing optics consisting of a lens system. On the other hand, however, a diaphragm (possibly integrated into a housing) situated at any distance before the "focusing optics" can also be considered an entrance pupil. Since such an entrance pupil can be placed in principle at any point in the beam path, even the illuminated diameter of a scanner mirror could be defined as "entrance pupil of the focusing optics". However, if a deflection mirror is used the feature would therefore be redundant and thus always fulfilled.

Claims 13, 14 and 19-22:

The use of the formulations "claim X in combination with one of claims Y to Z" and "according to claims X and Y" is unclear, since they do not clearly define the scope for which protection is sought. In both cases it is not clear from the choice of words whether protection is sought for **all** features of claim

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Box No. VIII Certain observations on the international application

X **and all** features of claim Y respectively and thus some features should be present twice, or whether the protection is claimed only for claim X with the features **additionally** present in claim Y.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box IV, Lack of unity of invention

This Authority has found that the international application contains 3 groups of inventions, which are not linked by a single general inventive concept (PCT Rule 13.1), namely:

- I: Claims 1-6, relating to a laser treatment apparatus with a safety mechanism which moves a head support and a contact lens apart above a force threshold value and fixes them relative to one another below the force threshold value.
- II: Claims 7-16, relating to a laser treatment apparatus with a safety mechanism which couples the contact lens, focusing optics and deflection element in such a way that on moving apart the deflection element remains in the entrance pupil.
- III: Claims 17-22, relating to a laser treatment apparatus with a safety mechanism which has a detector device.

Document EP0608052 (D4) is considered the closest prior art. The difference between the disclosure in document D4 and the three inventions can be defined as follows:

Claims 1-6: The difference between the subject matter of this group of claims and D4 is a safety mechanism which facilitates movement apart of the head support and contact lens only in the event of a force above a force threshold value, and in the event of a force below the

Supplemental Box

force threshold value fixes the two elements relative to one another. The problem to be addressed consists in providing a mechanism which guarantees a steady laser alignment below a maximum permitted eye inner pressure and adjusts the alignment only in extreme cases to protect the eye against damage.

Claims 7-16: This invention relates to a safety mechanism which couples the contact lens, the focusing optics and the deflection element in such a way that on moving apart the deflection element remains in the entrance pupil and the length of the optical path between the deflection element and the contact lens is constant. The problem to be addressed consists in this case in the design of a mechanism which keeps the laser beam path as unchanged as possible in a rotating movement.

Claims 17-22: This group of claims is concerned with a safety mechanism which has a detector device, which monitors a retreat of the contact lens. The problem to be addressed consists in the detection of the end of the adjustment range, in order to initiate an emergency shutdown.

In summary, the 3 groups of claims are not therefore linked by a common or corresponding special technical feature. The application does not therefore satisfy the requirements of unity as defined in PCT Rules 13.1 and 13.2.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input checked="" type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 14 August 2007 (14.08.2007) Authorized officer <p style="text-align: center; font-weight: bold;">Agnes Wittmann-Regis</p> e-mail: pt06.pct@wipo.int
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

TRANSLATION
PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

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FOR FURTHER ACTION

See paragraph 2 below

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International filing date (day/month/year)

10.01.2006

Priority date (day/month/year)

11.01.2005

International Patent Classification (IPC) or both national classification and IPC

A61F9/009

Applicant

CARL ZEISS MEDITEC AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
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3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Date of completion of this opinion

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2006/000145

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed
☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed
☐ filed together with the international application in electronic form
☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

☐ paid additional fees

☐ paid additional fees under protest and, where applicable, the protest fee

☐ paid additional fees under protest but the applicable protest fee was not paid

☐ not paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

See Supplemental Box

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6, 10, 11, 13, 14, 16, 19, 20, 22	YES
	Claims	7-9, 12, 15, 17, 18, 21	NO
Inventive step (IS)	Claims	10, 11, 14, 16, 19-20, 22	YES
	Claims	1-6, 7-9, 12, 13, 15, 17, 18, 21	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

2. Citations and explanations:

1 Citations

Reference is made to the following documents:

- D1: EP-A-0 589 825 (OPTIKO SCIENTIFIC LTD; OPTIKO SCIENT LTD) 30 March 1994 (1994-03-30)
- D2: US-A-5 217 452 (O'DONNELL ET AL) 8 June 1993 (1993-06-08)
- D3: DE 198 31 674 A1 (LASERFORUM GMBH FORUM FUER LASERCHIRURGIE DES AUGES - KOELN) 20 January 2000 (2000-01-20)
- D4: EP-A-0 608 052 (INTELLIGENT SURGICAL LASERS, INC) 27 July 1994 (1994-07-27)
- D5: EP-A-1 570 822 (20/10 PERFECT VISION OPTISCHE GERAETE GMBH) 7 September 2005 (2005-09-07)

2 Independent claim 1

- 2.1 The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 1 does not involve an inventive step (PCT Article 33(3)).

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2.2	Document D1 is considered to be the prior art closest to the subject matter of claim 1. Said document discloses:
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A laser treatment apparatus for eye surgery (column 2, lines 46-49), with a head support for a patient and a contact lens that can be placed onto the eye (column 4, lines 17-21), through which lens a treatment laser beam passes (column 4, lines 1-3), wherein a safety mechanism is provided, which moves the head support and the contact lens apart when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens (see "pressure control unit 53" in column 4, lines 21-28: the motor is controlled via the force measuring unit and can therefore be set so that the motor is not activated below a threshold value), characterized in that the safety mechanism facilitates the movement apart only in the event of a force above a force threshold value and in the event of a force below the force threshold value fixes the head support and the contact lens relative to one another (see "pressure control unit 53" in column 4, lines 21-28: since the "pressure control unit" measures the pressure applied to the eye and controls the motor depending on the measured value, any force threshold value can thus be set).

2.3	The subject matter of claim 1 differs therefore from that known from D1 in that the use of a chin or forehead support or other contact surface for
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the head is not explicitly mentioned.

However, the use of such a head contact surface is generally known. According to the examiner's knowledge, neither any apparatus for examining or treating the retina nor any apparatus in the Femtosecond Lasik field is currently in use that does not provide a head contact surface.

The presence of such a contact surface is therefore considered so obvious that it is no longer mentioned in the prior art for this reason alone. In the description of D2, cited here as an example, no details are given of a head support, but figures 3 and 4 show very well the presence of such a support.

- 2.4 The present application does not therefore satisfy the requirements of PCT Article 33(1), because the subject matter of claim 1 does not involve an inventive step (PCT Article 33(3)).

3 Independent claim 7

The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 7 is not novel (PCT Article 33(2)).

Document D4 discloses:

A laser treatment apparatus for eye surgery (abstract), with a head support for a patient (figures 1-3: it is implicitly disclosed that such a head support is present, as it cannot be assumed that the patient shown in the

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figures is floating in the air), a beam deflection unit, which deflects a treatment laser beam variably at least about one axis (see "means for moving said focal point along a preselected path relative to said contact lens to perform said surgery" in claim 1), focusing optics, which are arranged following the beam deflection unit and focus the laser beam into or onto the eye along an optical axis (column 3, lines 11-18 & lines 45-51 & figure 1), a contact lens that can be placed onto the eye and is arranged following the focusing optics (column 6, lines 8-23 & column 3, lines 7-10 & figure 1), and a safety mechanism, which moves the head support and the contact lens apart when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens ("compensating device; spring 36a,b" in column 5, lines 7-31), characterized in that the beam deflection unit is arranged at least with respect to a deflection element acting for one axis of deflection in the entrance pupil of the focusing optics (see the clarity objection in Box VIII relating to this; to the extent to which the feature is comprehensible, it appears to be disclosed in column 3, lines 7-18 and figures 1,2) and the safety mechanism couples the contact lens, the focusing optics and the deflection element such that on the movement apart the deflection element remains in the entrance pupil and the length of the optical path between the deflection element and the contact lens is constant (see the clarity objection in Box VIII relating to this; to the extent to which the feature is comprehensible, it appears to be disclosed in column 5, lines 1-6, in that "the relationship between housing 12 and base 28 of mechanism 16" is fixed).

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4 Independent claim 17

The present application does not satisfy the requirements of PCT Article 33(1), because the subject matter of claim 17 is not novel (PCT Article 33(2)).

Document D1 discloses:

A laser treatment apparatus for eye surgery (column 2, lines 46-49), with a contact lens that can be placed onto the eye (column 4, lines 17-21), through which lens a treatment laser beam passes (column 4, lines 1-3), and a safety mechanism, which holds the contact lens movably ("spring assembly 52" in column 4, lines 21-28 & lines 36-40 & figure 2), so that when a force opposite to the direction of incidence of the laser beam is directed onto the contact lens, this retreats (column 3, lines 22-31 & column 4, lines 17-28), characterized in that the safety mechanism has a detector device, which monitors a retreat of the contact lens ("pressure control unit 53" in column 4, lines 21-28 & figure 2) and in the event of a movement of the contact lens exceeding a threshold value interrupts a laser treatment operation of the laser treatment apparatus (column 3, lines 22-31 & column 4, lines 17-28).

5 Dependent claims 8-9, 12, 15, 18, 21

Claims 8-9, 12, 15, 18, 21 do not contain any features which, in combination with the features of any claim to which they refer back, satisfy the PCT requirements for novelty.

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Box No. V

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Claim 8: See D4, column 2, line 41 - column 3, line 6.

Claim 9: See D4, column 2, line 41 - column 3, line 18.

Claim 12: See "linear spring force" in column 2, lines
52-57 in D4.

Claim 15: See D4: a force on the "frame member" in column
2, line 41 - column 3, line 6 causes a movement
apart of the safety mechanism.

Claim 18: See D1: the "pressure control unit 53" in
column 4, lines 17-28 is suitable for moving
the contact lens and eye apart as soon as a
predetermined force threshold value is reached.

Claim 21: As shown in figure 2 of document D1, the
pressure detector is fastened to the housing
and thus detects the pressure of the eye onto
the housing. See also column 3, lines 22-31 &
column 4, lines 17-28.

6 Dependent claims 2-5,13

Claims 2-5,13 do not contain any features which, in
combination with the features of any claim to which they
refer back, satisfy the PCT requirements for inventive
step.

Claim 2: See D1: column 4, lines 21-28 & figure 1.

Claim 3: See D1, "measurement of pressure" in column 4,
lines 21-28.

Claim 4: See D1: the "spring assembly 52", column 4,
lines 17-28 and figure 2, is pressed with a
force onto the holding element "housing 2b",
column 4, lines 17-21. If a predefined force is

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exceeded, the motor "M" is set in motion.

Claim 5: See D1, "treating the eye..." in column 2, lines 46-49: if an eye is to be treated with the laser beam, it is implicitly disclosed that the beam must be focused, otherwise meaningful treatment would not be possible.

Claim 6: See D4, column 5, line 26.

Claim 13: See D3, column 4, lines 43-47. It is provided that the "magnetic current [is] electronically monitored", thus the force threshold value can be set via the magnetic current.

7 Dependent claim 22

Document EP1570822 (D5) is cited as a "P" document and is thus not relevant as prior art if the claimed priority is valid. However, since no valid priority document exists up to now and the validity of the priority cannot therefore be verified, the applicant is hereby advised of objections possibly resulting with regard to inventive step in connection with document EP0608052 (D4) in respect of claim 22:

Claim 22: See also clarity objection in Box VIII.

Notwithstanding this, D5 discloses in paragraph [0041] that, on attaining a certain force value, no further approach of the chair to the laser is possible. Rather only an active increase in this distance between eye and laser is provided.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
EP1570822	07.09.2005	17.01.2005	1.03.2004

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The application does not satisfy the requirements of PCT Article 6, because claims 7, 13, 14 and 19-22 are not clear.

Claim 7: The claim is unclear, since there is no clear definition of the term "entrance pupil of focusing optics": on the one hand, the illuminated diameter of the first lens could be considered the entrance pupil of the focusing optics consisting of a lens system. On the other hand, however, a diaphragm (possibly integrated into a housing) situated at any distance before the "focusing optics" can also be considered an entrance pupil. Since such an entrance pupil can be placed in principle at any point in the beam path, even the illuminated diameter of a scanner mirror could be defined as "entrance pupil of the focusing optics". However, if a deflection mirror is used the feature would therefore be redundant and thus always fulfilled.

Claims 13, 14 and 19-22:

The use of the formulations "claim X in combination with one of claims Y to Z" and "according to claims X and Y" is unclear, since they do not clearly define the scope for which protection is sought. In both cases it is not clear from the choice of words whether protection is sought for **all** features of claim

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Box No. VIII

Certain observations on the international application

X **and all** features of claim Y respectively and thus some features should be present twice, or whether the protection is claimed only for claim X with the features **additionally** present in claim Y.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box IV, Lack of unity of invention

This Authority has found that the international application contains 3 groups of inventions, which are not linked by a single general inventive concept (PCT Rule 13.1), namely:

- I: Claims 1-6, relating to a laser treatment apparatus with a safety mechanism which moves a head support and a contact lens apart above a force threshold value and fixes them relative to one another below the force threshold value.
- II: Claims 7-16, relating to a laser treatment apparatus with a safety mechanism which couples the contact lens, focusing optics and deflection element in such a way that on moving apart the deflection element remains in the entrance pupil.
- III: Claims 17-22, relating to a laser treatment apparatus with a safety mechanism which has a detector device.

Document EP0608052 (D4) is considered the closest prior art. The difference between the disclosure in document D4 and the three inventions can be defined as follows:

Claims 1-6: The difference between the subject matter of this group of claims and D4 is a safety mechanism which facilitates movement apart of the head support and contact lens only in the event of a force above a force threshold value, and in the event of a force below the

Supplemental Box

force threshold value fixes the two elements relative to one another. The problem to be addressed consists in providing a mechanism which guarantees a steady laser alignment below a maximum permitted eye inner pressure and adjusts the alignment only in extreme cases to protect the eye against damage.

Claims 7-16: This invention relates to a safety mechanism which couples the contact lens, the focusing optics and the deflection element in such a way that on moving apart the deflection element remains in the entrance pupil and the length of the optical path between the deflection element and the contact lens is constant. The problem to be addressed consists in this case in the design of a mechanism which keeps the laser beam path as unchanged as possible in a rotating movement.

Claims 17-22: This group of claims is concerned with a safety mechanism which has a detector device, which monitors a retreat of the contact lens. The problem to be addressed consists in the detection of the end of the adjustment range, in order to initiate an emergency shutdown.

In summary, the 3 groups of claims are not therefore linked by a common or corresponding special technical feature. The application does not therefore satisfy the requirements of unity as defined in PCT Rules 13.1 and 13.2.